

Economic Impact Statement
LSA Document #10-504

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses**Description of Rule**

According to [IC 16-41-17-2](#), the Indiana State Department of Health (Department) is responsible for ensuring that all infants born in Indiana are screened for the disorders currently on the Indiana newborn screening panel. In addition, [IC 16-41-17-10](#) charges the Department with providing diagnosis, follow-up, management, family counseling, and support (including equipment, supplies, formula, and other materials) for all infants and individuals identified as having any of these conditions. According to [IC 16-41-17-9](#), the Department shall adopt rules to carry out this chapter, including rules to ensure: a) proper timely sample collection and transportation, b) quality testing procedures for the laboratory, and c) uniform reporting procedures. [410 IAC 3-3](#) was created to fulfill this requirement.

This rule change would amend [410 IAC 3-3](#) to add new and update current definitions; add requirements for the designated laboratory to furnish filter paper kits for collection of newborn screening specimens to collection sources and designate other payers for equipment and supplies; add screening requirements for additional conditions; add specimen collection modifications for physicians and hospitals; update screening requirements and reporting requirements for the designated laboratory; update requirements for hospitals, birthing centers, midwives, and physicians providing home birth services to maintain a screening log, perform follow-up services, and submit a monthly report to the Department; update procedures for follow-up of positive screening results; and update fee schedules for repeat screenings. This rule also amends [410 IAC 3-3](#) to include requirements for appropriate newborn hearing screenings, establish newborn hearing screening responsibilities and hearing screening protocols, and establish requirements for newborn hearing screening follow-up and reports.

Economic Impact on Small Businesses**1. Estimate of the number of small businesses, classified by industry sector, that will be subject to the proposed rule.**

[IC 4-22-2.1-4](#) defines a small business as any person, firm, corporation, limited liability company, partnership, or association that:

- (1) is actively engaged in business in Indiana and maintains its principal place of business in Indiana;
- (2) is independently owned and operated;
- (3) employs one hundred (100) or fewer full-time employees; and
- (4) has gross annual receipts of five million dollars (\$5,000,000) or less.

This proposed rule change would directly affect the state-contracted NBS lab and the state's 101 birthing facilities (both hospitals and midwiferies), including the facilities' staff of physicians, nurse practitioners, and audiologists. It is difficult to provide an accurate estimate of the total number of small businesses that would be impacted by this rule amendment. The vast majority of physicians, nurse practitioners, and audiologists who report to ISDH under this rule are part of the staff at one of the state's birthing facilities. Some of the 101 birthing facilities (specifically midwiferies) could be classified as small businesses, and there may be a small number of physicians, nurse practitioners, or audiologists in private practice that would be affected by this rule amendment. Overall, it is anticipated that not more than 101 facilities would be impacted by this rule amendment.

2. Estimate of the average annual reporting, record keeping, and other administrative costs that small businesses will incur to comply with the proposed rule.

Small businesses may incur minimal costs for reporting, record keeping, or other administrative costs as a result of this amendment. Overall, no increased cost is expected to result from adoption of this proposed rule change. The amendments included in the proposed rule change were written to bring the current version of [410 IAC 3-3](#) into compliance with statutory requirements and to reflect current program performance and protocols. No additional tasks or duties for small businesses were added.

3. Estimate of the total annual economic impact that compliance with the proposed rule will have on all small businesses subject to the rule.

It is anticipated that small businesses will incur minimal costs for compliance with this rule, as all of the businesses impacted by the proposed rule change are already performing newborn screening and reporting to ISDH based on current program standards and policies. Again, the amendments included in the proposed rule change were written to bring the current version of [410 IAC 3-3](#) into compliance with statutory requirements and to reflect current program performance. No additional tasks or duties for small businesses were added.

Some birthing facilities may have expenditures related to purchasing, updating, and/or maintaining hearing screening equipment as outlined in the proposed rule change. In order to offset these costs, the ISDH

Newborn Screening Program has purchased 13 hearing screening units with funding obtained through a Human Resources Services Administration (HRSA) grant and has made this equipment available to birthing facilities, free of charge, as "loaner equipment". As of July 2011, nine birthing facilities (out of 101 total birthing facilities) had completed the required paperwork. All nine facilities have been or will be awarded loaner equipment. Based on the low number of birthing facilities that have expressed interest in obtaining the loaner equipment, the ISDH Newborn Screening Program believes that most birthing facilities and audiology facilities already have screening and diagnostic equipment available and are already maintaining or updating this equipment as needed. Therefore, the overall cost of compliance for hearing screening would be minimal or negligible. If this rule is adopted and birthing facilities have difficulty obtaining or maintaining hearing screening equipment, the ISDH Newborn Screening Program is willing and prepared to offer assistance through an extended loaner equipment program.

4. Statement justifying any requirement or cost that is imposed on small businesses by the rule; and not expressly required by the statute authorizing the agency to adopt the rule; or any other state or federal law.

This rule does not impose any additional requirements or costs on small businesses not expressly required by the authorizing statute.

5. Regulatory Flexibility Analysis

Other factors considered:

A. Establishment of less stringent compliance or reporting requirements for small businesses.

The least stringent means have been utilized in this rule. A new web-based application has been developed by the ISDH Newborn Screening Program and will serve as a central repository for newborn screening reporting. All birthing facilities have been or will be trained to utilize this web-based application by the end of 2011. By requiring reporting into a central repository, any additional reporting by small businesses under this rule has been eliminated. All quality assurance or follow-up by ISDH can be accomplished from the central repository and will not require any additional efforts on the part of the licensees.

B. Establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

All entities affected by this proposed rule change, regardless of size, are required to adhere to the rules outlined in this proposal. Compliance activities will not require any additional action by small businesses because the central repository will have all of the needed information for ISDH staff to be able to perform any needed quality assurance measures.

C. Consolidation or simplification of compliance or reporting requirements for small businesses.

The ISDH Newborn Screening Program has simplified reporting requirements and compliance for all entities, regardless of size, by developing a central repository (via a web-based application) that is used by birthing facilities to complete all required reports. This application also gives ISDH and birthing facilities the ability to generate reports as required by state and federal rules. Compliance activities will not require any additional action by small businesses because the central repository will have all of the needed information for ISDH staff to be able to perform any needed quality assurance measures.

D. Establishment of performance standards for small businesses instead of design or operational standards imposed on other regulated entities by the rule.

The proposed rule change involves both performance standards and design standards. The rule includes specific design standards that outline program practices (including proper time and method of collecting a newborn screening sample, proper time and method for performing newborn hearing screening, reporting requirements, etc.). Whenever possible, the ISDH Newborn Screening Program has allowed flexibility for small businesses and other stakeholders when moving into compliance with this proposed rule change (for example, ISDH Newborn Screening Program does not specify what brand of hearing screening equipment birthing facilities must purchase). These design standards are directly related to the overall performance standards that are desired by the ISDH Newborn Screening Program, which include the following: 1) ensuring that all infants born in Indiana receive an accurate, valid, and timely newborn screen; 2) ensuring that all infants with an abnormal or presumptive positive newborn screen receive timely and effective follow-up services, including treatment; and 3) avoiding negative long-term health outcomes (including physical or mental disability or death) for infants confirmed to have a condition on the newborn screening panel. All entities affected by the proposed rule change will be required to adhere to the same performance and design standards, regardless of the size of the entity.

E. Exemption of small businesses from part or all of the requirements or costs imposed by the rule.

The proposed rule change will only apply to those health care providers directly involved in providing newborn screening and who can be classified as a small business, including birthing facilities (hospitals and midwiferies), physicians, nurse practitioners, and audiologists in private practice. No other small businesses are affected.

Conclusion

The proposed rule change has minimal economic impact on small businesses. It is anticipated that some small businesses may incur minimal costs for compliance with this rule. Some birthing facilities, however, may have expenditures related to purchasing, updating, and/or maintaining hearing screening equipment as outlined in the proposed rule change. In order to offset these costs, the ISDH Newborn Screening Program has purchased 13 hearing screening units with funding obtained through a Human Resources Services Administration (HRSA) grant and has made this equipment available to birthing facilities, free of charge, as "loaner equipment". ISDH is willing to extend this loaner equipment program as necessary if this rule is adopted and birthing facilities have difficulty obtaining or maintaining hearing screening equipment.

It should be noted that all of the entities impacted by the proposed rule change, regardless of size, currently perform newborn screening and report to ISDH based on current program standards and policies. The amendments included in the proposed rule change were written to bring the current version of [410 IAC 3-3](#) into compliance with statutory requirements and to reflect current program performance. No additional tasks or duties for small businesses were added.

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